

## **REMARKS**

Applicant respectfully requests reconsideration of this application in view of the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in substantially the same order in which the corresponding issues were raised in the Office Action.

### **IDS References**

As a preliminary matter, Applicant expresses appreciation to the Examiner for initialing a copy of the PTO-1449 form references mailed to the PTO on September 4, 2004. The initialed copy was received with the former Office Action mailed March 9, 2006 (now withdrawn).

### **Interview Summary**

Applicant also expresses appreciation to the Examiner for withdrawing the Office Action mailed March 9, 2006, and sending the Interview Summary via facsimile on June 8, 2006. Applicant agrees with the content of the Interview Summary.

### **Status of the Claims**

Claims 30-57, 59-61, and 63-65 are pending. Claim 30 is currently amended. No claims are canceled. No claims are added. No new matter has been added.

### **Summary of the Office Action**

Claims 30-57, 59-61, and 63-65 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,356,782 to Sirimanne et al. (hereinafter "Sirimanne") in view of U.S. Patent Application No. 6,144,875 to Schweikard et al. (hereinafter "Schweikard").

### **Response to Rejections under 35 U.S.C. § 103(a)**

The Office Action rejected claims 30-57, 59-61, and 63-65 under 35 U.S.C. § 103(a) as being unpatentable over Sirimanne in view of Schweikard. Applicant

respectfully requests withdrawal of these rejections because the cited reference fails to teach or suggest all of the limitations of the claims.

#### CLAIMS 30-35

Claim 30 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Sirimanne in view of Schweikard. Applicant respectfully submits that claim 30 is patentable over the cited references because the combination of Sirimanne and Schweikard does not teach or suggest all of the limitations of the claim. Claim 30, as amended, recites:

A method, comprising:

depositing a fiducial into a target region of a patient, wherein **the fiducial comprises a body portion and an anchor member coupled to the body portion, the body portion having a housing, the anchor member drawn into the housing in an unanchored position;**

detecting the fiducial using electromagnetic radiation to locate the target region of the patient; and

performing stereotaxic radiosurgery on the target region of the patient according to the detected fiducial and the location of the target region.

(Emphasis added).

Applicant respectfully submits Sirimanne and Schweikard fail to teach or suggest all of the limitations of the claim. In particular, the combination of Sirimanne and Schweikard does not teach or suggest the fiducial comprising a body portion and an anchor member coupled to the body portion, the body portion having a housing, the anchor member drawn into the housing in an unanchored position.

Sirimanne is directed to a marking device that may be inserted into a subcutaneous cavity to expand within the cavity and mark the cavity. Sirimanne, Abstract. The marker enables someone to determine the location, orientation, and periphery of the cavity. Sirimanne, col. 1, lines 10-17. The marking device includes a body and a marker. Sirimanne, col. 7, lines 1-31. Sirimanne teaches several types of bodies and markers, such as a spherical body 102 and a centrally located mark 150. Sirimanne, col. 7, lines 26-43. Sirimanne also teaches a substantially spherical body 158 made of suture material looped through a marker 154. Sirimanne, col. 9, lines 34-51. Furthermore, Sirimanne teaches that the body anchors the marking device, including the body and marker, within the cavity. Sirimanne, col. 5, lines 4-20. Therefore, the body

anchors itself, along with the marker, within the cavity. Given that the body is also the anchoring mechanism, it would not be reasonable to assert that the body has a housing that houses itself as the anchor. Accordingly, Sirimanne does not teach or suggest the body having a housing of any sort and, in particular, a housing that houses an anchor member.

Schweikard is directed to a system to compensate for patient breathing during radiation treatment. Schweikard, Abstract. Internal markers are attached to the target organ to track the movement of the target organ during treatment. Schweikard, col. 5, lines 31-46. However, Schweikard does not disclose a fiducial having a body portion and an anchor, as recited in the claim. Schweikard merely discloses internal markers, generally, and explains that the internal markers are attached to a target organ. Figures 5-8 use generic circles to illustrate the internal markers, but do not show any type of housing or anchor members. Therefore, Schweikard does not disclose a fiducial comprising a body portion, having a housing, and an anchor member coupled to the body portion.

In contrast, claim 30 recites “the fiducial comprising a body portion and an anchor member coupled to the body portion, the body portion having a housing, the anchor member drawn into the housing in an unanchored position.” For the reasons stated above, the combination of cited references fails to teach or suggest all of the limitations of claim 30. In particular, the combination of cited references does not teach or suggest the fiducial comprising a body portion and an anchor member coupled to the body portion, the body portion having a housing, the anchor member drawn into the housing in an unanchored position. Given that the cited references fail to teach or suggest all of the limitations of the claim, Applicant respectfully submits that claim 30 is patentable over the cited references. Accordingly, Applicant requests that the rejection of claim 30 under 35 U.S.C. § 103(a) be withdrawn.

Given that claims 31-35 depend from independent claim 30, which is patentable over the cited references, Applicant respectfully submits that dependent claims 31-35 are also patentable over the cited references. Accordingly, Applicant requests that the rejection of claims 31-35 under 35 U.S.C. § 103(a) be withdrawn.

## CLAIMS 36-45

Claim 36 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Sirimanne in view of Schweikard. Applicant respectfully submits that claim 36 is patentable over the cited references because the combination of cited references does not teach or suggest all of the limitations of the claim. Claim 36 recites:

A fiducial apparatus, comprising:

**a body portion having a housing**, the body portion comprising a material visible using electromagnetic radiation; and  
an anchor member coupled to the body portion, the anchor member having an unanchored position and an anchored position, **the anchor member drawn into the housing in the unanchored position** and withdrawn from the housing in the anchored position.

(Emphasis added).

In support of the rejection, the Office Action states, in part:

Sirimanne et al disclose the markers being anchored to the area of interest via **wire or suture** introduced from the same lumen where the markers are placed in the region of interest. And since the suture or wire is introduced after the markers are placed in the region of interest, it is interpreted as having unanchored position prior to affixing the markers to the surrounding tissue, i.e., anchored position (col. 6, lines 56-67). In addition, the shape and composition of the anchors as described in the applicant's claims 37-43 are design choice where the end result of the anchoring is **functionally equivalent** to Sirimanne et al's anchoring apparatus.

Office Action, June 15, 2006, pp. 3-4 (emphasis added).

Applicant respectfully disagrees with the Office Action's characterization of the prior art because Sirimanne fails to teach or suggest all of the limitations of the claim. In particular, Sirimanne does not teach or suggest a fiducial apparatus comprising a body portion having a housing. Additionally, Sirimanne does not teach or suggest an anchor member drawn into the housing in an unanchored position.

As mentioned in the Office Action, Sirimanne discloses using a wire or a suture. However, the Office Action seems to indicate that the wire or suture is both a body and an anchor of the marker. In the proper context, Sirimanne merely discloses that the marker itself may be a wire or suture, which may be woven into the body cavity. Sirimanne, col. 6, lines 61-62 (which states "in the case where the marker is a wire or suture" (emphasis added)). If the wire or suture is purported to be the body of the marker, then Sirimanne fails to teach or suggest the wire or suture having a housing.

Alternatively, if the wire or suture is purported to be the anchor, then Sirimanne fails to teach or suggest a body portion having a housing in which the wire or suture may be drawn into in an unanchored position. Thus, the wire or suture cannot simultaneously be considered a body and an anchor. Accordingly, either interpretation of the Office Action results in insufficient disclosure by Sirimanne.

Also, in case the Office Action purports that the lumen is a housing, Applicant notes that the lumen, or access device, is not a housing of the body portion of the marker. Sirimanne explains that the access device is not the marking device, but is used to percutaneously deliver the marking device. Sirimanne, col. 12, lines 45-52. Examples of the access device are a catheter and a delivery tube. These devices are clearly not fiducial markers. Thus, the housing of the access device, or lumen, is not a housing of a fiducial marker. Moreover, even if the housing of the access device were a housing of a fiducial marker, Sirimanne does not disclose the access device housing as being a material visible using electromagnetic radiation. Regardless of the material of the access device, though, Sirimanne nevertheless fails to disclose a fiducial apparatus comprising a body portion having a housing.

Schweikard also does not disclose a fiducial having a body portion and an anchor, as recited in the claim. Schweikard merely discloses internal markers, generally, but does not appear to describe any particular implementation. Thus Schweikard also does not teach or suggest a fiducial apparatus comprising a body portion having a housing.

Moreover, even if the marker of Sirimanne were to have a body portion and a housing, the methods for affixing the marker of Sirimanne are not functionally equivalent to the fiducial recited in the claim. Although many differences exist, one exemplary difference between the marker of Sirimanne and the fiducial recited in the claim is the way in which each is inserted into the body. The marker of Sirimanne is inserted into a biopsy cavity and expands to fill the cavity, is woven into the body, or is affixed by a biocompatible adhesive. In contrast, the fiducial of the recited claim does not operate by expanding to fill a cavity, is not woven into the body, and is does not require an adhesive. In particular, weaving the marker into the body of the patient, or applying an adhesive to the marker, would potentially add considerable complexity to the process of inserting the claimed fiducial into the body of a patient. As for the expandable marker of Sirimanne,

the expandable marker is described as being inserted into a biopsy cavity, and there is no indication that the expandable marker could be inserted into a tumor or other non-cavity part of the body. Thus, the affixation means of Sirimanne are not functionally equivalent to the structure recited in the claim. Furthermore, even if the affixation means of Sirimanne were functionally equivalent to the anchor recited in the claim, Sirimanne nevertheless fails to disclose a body portion having a housing.

In contrast, claim 36 recites “a body portion having a housing” and an “anchor member drawn into the housing in the unanchored position.” For the reasons stated above, Sirimanne fails to disclose all of the limitations of claim 36. In particular, the combination of cited references does not disclose a fiducial apparatus comprising a body portion having a housing. The combination of cited references also does not teach or suggest an anchor member drawn into the housing in an unanchored position. Given that the cited references fail to disclose all of the limitations of the claim, Applicant respectfully submits that claim 36 is patentable over the cited references. Accordingly, Applicant requests that the rejection of claim 36 under 35 U.S.C. § 103(a) be withdrawn.

Given that claims 37-45 depend from independent claim 36, which is patentable over the cited references, Applicant respectfully submits that dependent claims 37-45 are also patentable over the cited references. Accordingly, Applicant requests that the rejection of claims 37-45 under 35 U.S.C. § 103(a) be withdrawn.

#### CLAIMS 46-51

Claim 46 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Sirimanne in view of Schweikard. Applicant respectfully submits that claim 46 is patentable over the cited references because the combination of Sirimanne and Schweikard does not teach or suggest all of the limitations of the claim. Claim 46 recites:

A method, comprising:

inserting an insertion needle into a tissue target region of a patient, the insertion needle containing a fiducial in an unanchored position, **the fiducial comprising a body portion and an anchor member coupled to the body portion, the body portion having a housing, the anchor member drawn into the housing in the unanchored position;**

displacing a portion of the tissue target region; and

depositing the fiducial into the tissue target region, the anchor member withdrawing from the housing and embedding in the tissue target region in response to the fiducial exiting the insertion needle. (Emphasis added).

Applicant respectfully submits Sirimanne and Schweikard fail to teach or suggest all of the limitations of the claim. In particular, the combination of Sirimanne and Schweikard does not teach or suggest the fiducial comprising a body portion and an anchor member coupled to the body portion, the body portion having a housing, the anchor member drawn into the housing in the unanchored position.

Sirimanne is directed to a marking device that may be inserted into a subcutaneous cavity to expand within the cavity and mark the cavity. Sirimanne, Abstract. The marker enables someone to determine the location, orientation, and periphery of the cavity. Sirimanne, col. 1, lines 10-17. The marking device includes a body and a marker. Sirimanne, col. 7, lines 1-31. Sirimanne teaches several types of bodies and markers, such as a spherical body 102 and a centrally located mark 150. Sirimanne, col. 7, lines 26-43. Sirimanne also teaches a substantially spherical body 158 made of suture material looped through a marker 154. Sirimanne, col. 9, lines 34-51. Furthermore, Sirimanne teaches that the body anchors the marking device, including the body and marker, within the cavity. Sirimanne, col. 5, lines 4-20. Therefore, the body anchors itself, along with the marker, within the cavity. Given that the body is also the anchoring mechanism, it would not be reasonable to assert that the body has a housing that houses itself as the anchor. Accordingly, Sirimanne does not teach or suggest the body having a housing of any sort and, in particular, a housing that houses an anchor member.

Schweikard is directed to a system to compensate for patient breathing during radiation treatment. Schweikard, Abstract. Internal markers are attached to the target organ to track the movement of the target organ during treatment. Schweikard, col. 5, lines 31-46. However, Schweikard does not disclose a fiducial having a body portion and an anchor, as recited in the claim. Schweikard merely discloses internal markers, generally, and explains that the internal markers are attached to a target organ. Figures 5-8 use generic circles to illustrate the internal markers, but do not show any type of housing or anchor members. Therefore, Schweikard does not disclose a fiducial

comprising a body portion, having a housing, and an anchor member coupled to the body portion.

In contrast, claim 46 recites “the fiducial comprising a body portion and an anchor member coupled to the body portion, the body portion having a housing, the anchor member drawn into the housing in the unanchored position.” For the reasons stated above, the combination of cited references fails to teach or suggest all of the limitations of claim 46. In particular, the combination of cited references does not teach or suggest the fiducial comprising a body portion and an anchor member coupled to the body portion, the body portion having a housing, the anchor member drawn into the housing in the unanchored position. Given that the cited references fail to teach or suggest all of the limitations of the claim, Applicant respectfully submits that claim 46 is patentable over the cited references. Accordingly, Applicant requests that the rejection of claim 46 under 35 U.S.C. § 103(a) be withdrawn.

Given that claims 47-51 depend from independent claim 46, which is patentable over the cited references, Applicant respectfully submits that dependent claims 47-51 are also patentable over the cited references. Accordingly, Applicant requests that the rejection of claims 47-51 under 35 U.S.C. § 103(a) be withdrawn.

#### CLAIMS 52-56

Claim 52 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Sirimanne in view of Schweikard. Applicant respectfully submits that claim 52 is patentable over the cited references because the combination of Sirimanne and Schweikard does not teach or suggest all of the limitations of the claim. Claim 52 recites:

A fiducial apparatus, comprising:

means for coupling an anchor member to a body portion, **the body portion having a housing, the anchor member drawn into the housing in an unanchored position;**

means for displacing a portion of a tissue target region; and

means for embedding the anchor member in the tissue target region.

(Emphasis added).

Applicant respectfully submits Sirimanne and Schweikard fail to teach or suggest all of the limitations of the claim. In particular, the combination of Sirimanne and



Schweikard does not teach or suggest the body portion having a housing, the anchor member drawn into the housing in an unanchored position.

Sirimanne is directed to a marking device that may be inserted into a subcutaneous cavity to expand within the cavity and mark the cavity. Sirimanne, Abstract. The marker enables someone to determine the location, orientation, and periphery of the cavity. Sirimanne, col. 1, lines 10-17. The marking device includes a body and a marker. Sirimanne, col. 7, lines 1-31. Sirimanne teaches several types of bodies and markers, such as a spherical body 102 and a centrally located mark 150. Sirimanne, col. 7, lines 26-43. Sirimanne also teaches a substantially spherical body 158 made of suture material looped through a marker 154. Sirimanne, col. 9, lines 34-51. Furthermore, Sirimanne teaches that the body anchors the marking device, including the body and marker, within the cavity. Sirimanne, col. 5, lines 4-20. Therefore, the body anchors itself, along with the marker, within the cavity. Given that the body is also the anchoring mechanism, it would not be reasonable to assert that the body has a housing that houses itself as the anchor. Accordingly, Sirimanne does not teach or suggest the body having a housing of any sort and, in particular, a housing that houses an anchor member.

Schweikard is directed to a system to compensate for patient breathing during radiation treatment. Schweikard, Abstract. Internal markers are attached to the target organ to track the movement of the target organ during treatment. Schweikard, col. 5, lines 31-46. However, Schweikard does not disclose a fiducial having a body portion and an anchor, as recited in the claim. Schweikard merely discloses internal markers, generally, and explains that the internal markers are attached to a target organ. Figures 5-8 use generic circles to illustrate the internal markers, but do not show any type of housing or anchor members. Therefore, Schweikard does not disclose a fiducial comprising a body portion, having a housing, and an anchor member coupled to the body portion.

In contrast, claim 52 recites “the body portion having a housing, the anchor member drawn into the housing in an unanchored position.” For the reasons stated above, the combination of cited references fails to teach or suggest all of the limitations of claim 52. In particular, the combination of cited references does not teach or suggest

the body portion having a housing, the anchor member drawn into the housing in an unanchored position. Given that the cited references fail to teach or suggest all of the limitations of the claim, Applicant respectfully submits that claim 52 is patentable over the cited references. Accordingly, Applicant requests that the rejection of claim 52 under 35 U.S.C. § 103(a) be withdrawn.

Given that claims 53-56 depend from independent claim 52, which is patentable over the cited references, Applicant respectfully submits that dependent claims 53-56 are also patentable over the cited references. Accordingly, Applicant requests that the rejection of claims 53-56 under 35 U.S.C. § 103(a) be withdrawn.

#### CLAIMS 57, 59-60

Claim 57 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Sirimanne in view of Schweikard. Applicant respectfully submits that claim 57 is patentable over the cited references because the combination of Sirimanne and Schweikard does not teach or suggest all of the limitations of the claim. Claim 57 recites:

A fiducial apparatus, comprising:

an elastic body portion having an unanchored position and an anchored position, **the elastic body portion expandable to receive a material in an internal cavity** in the anchored position, the material visible using electromagnetic radiation.

(Emphasis added).

Applicant respectfully submits Sirimanne and Schweikard fail to teach or suggest all of the limitations of the claim. In particular, the combination of Sirimanne and Schweikard does not teach or suggest the elastic body portion expandable to receive a material in an internal cavity.

Sirimanne is directed to a marking device that may be inserted into a subcutaneous cavity to expand within the cavity and mark the cavity. Sirimanne, Abstract. The marker enables someone to determine the location, orientation, and periphery of the cavity. Sirimanne, col. 1, lines 10-17. The marking device includes a body and a marker. Sirimanne, col. 7, lines 1-31. Sirimanne teaches several types of bodies and markers, such as a spherical body 102 and a centrally located mark 150. Sirimanne, col. 7, lines 26-43. Sirimanne also teaches a substantially spherical body 158 made of suture material looped through a marker 154. Sirimanne, col. 9, lines 34-51.

Furthermore, Sirimanne teaches that the body anchors the marking device, including the body and marker, within the cavity. Sirimanne, col. 5, lines 4-20. Therefore, the body anchors itself, along with the marker, within the cavity. Given that the body is also the anchoring mechanism, it would not be reasonable to assert that the body has a housing that houses itself as the anchor. Accordingly, Sirimanne does not teach or suggest the elastic body portion expandable to receive a material in an internal cavity.

Schweikard is directed to a system to compensate for patient breathing during radiation treatment. Schweikard, Abstract. Internal markers are attached to the target organ to track the movement of the target organ during treatment. Schweikard, col. 5, lines 31-46. However, Schweikard does not disclose a fiducial having a body portion and an anchor, as recited in the claim. Schweikard merely discloses internal markers, generally, and explains that the internal markers are attached to a target organ. Figures 5-8 use generic circles to illustrate the internal markers, but do not show any type of housing or anchor members. Therefore, Schweikard does not teach or suggest the elastic body portion expandable to receive a material in an internal cavity.

In contrast, claim 57 recites “the elastic body portion expandable to receive a material in an internal cavity.” For the reasons stated above, the combination of cited references fails to teach or suggest all of the limitations of claim 57. In particular, the combination of cited references does not teach or suggest the elastic body portion expandable to receive a material in an internal cavity. Given that the cited references fail to teach or suggest all of the limitations of the claim, Applicant respectfully submits that claim 57 is patentable over the cited references. Accordingly, Applicant requests that the rejection of claim 57 under 35 U.S.C. § 103(a) be withdrawn.

Given that claims 59-60 depend from independent claim 57, which is patentable over the cited references, Applicant respectfully submits that dependent claims 59-60 are also patentable over the cited references. Accordingly, Applicant requests that the rejection of claims 59-60 under 35 U.S.C. § 103(a) be withdrawn.

#### CLAIMS 61, 63-65

Claim 61 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Sirimanne in view of Schweikard. Applicant respectfully submits that claim 61 is

patentable over the cited references because the combination of Sirimanne and Schweikard does not teach or suggest all of the limitations of the claim. Claim 61 recites:

A method, comprising:  
    inserting a fiducial in an unanchored position into a target tissue region, the fiducial comprising an elastic body portion defining an internal cavity;  
    displacing a portion of the tissue target region; and  
    **depositing a material into the internal cavity of the elastic body portion** to expand and anchor the elastic body portion within the tissue target region, the material visible using electromagnetic radiation.  
(Emphasis added).

Applicant respectfully submits Sirimanne and Schweikard fail to teach or suggest all of the limitations of the claim. In particular, the combination of Sirimanne and Schweikard does not teach or suggest depositing a material into the internal cavity of the elastic body portion.

Sirimanne is directed to a marking device that may be inserted into a subcutaneous cavity to expand within the cavity and mark the cavity. Sirimanne, Abstract. The marker enables someone to determine the location, orientation, and periphery of the cavity. Sirimanne, col. 1, lines 10-17. The marking device includes a body and a marker. Sirimanne, col. 7, lines 1-31. Sirimanne teaches several types of bodies and markers, such as a spherical body 102 and a centrally located mark 150. Sirimanne, col. 7, lines 26-43. Sirimanne also teaches a substantially spherical body 158 made of suture material looped through a marker 154. Sirimanne, col. 9, lines 34-51. Furthermore, Sirimanne teaches that the body anchors the marking device, including the body and marker, within the cavity. Sirimanne, col. 5, lines 4-20. Therefore, the body anchors itself, along with the marker, within the cavity. Given that the body is also the anchoring mechanism, it would not be reasonable to assert that the body has a housing that houses itself as the anchor. Accordingly, Sirimanne does not teach or suggest depositing a material into the internal cavity of the elastic body portion.

Schweikard is directed to a system to compensate for patient breathing during radiation treatment. Schweikard, Abstract. Internal markers are attached to the target organ to track the movement of the target organ during treatment. Schweikard, col. 5, lines 31-46. However, Schweikard does not disclose a fiducial having a body portion and an anchor, as recited in the claim. Schweikard merely discloses internal markers,

generally, and explains that the internal markers are attached to a target organ. Figures 5-8 use generic circles to illustrate the internal markers, but do not show any type of housing or anchor members. Therefore, Schweikard does not teach or suggest depositing a material into the internal cavity of the elastic body portion.

In contrast, claim 61 recites “depositing a material into the internal cavity of the elastic body portion.” For the reasons stated above, the combination of cited references fails to teach or suggest all of the limitations of claim 61. In particular, the combination of cited references does not teach or suggest depositing a material into the internal cavity of the elastic body portion. Given that the cited references fail to teach or suggest all of the limitations of the claim, Applicant respectfully submits that claim 61 is patentable over the cited references. Accordingly, Applicant requests that the rejection of claim 61 under 35 U.S.C. § 103(a) be withdrawn.

Given that claims 63-65 depend from independent claim 61, which is patentable over the cited references, Applicant respectfully submits that dependent claims 63-65 are also patentable over the cited references. Accordingly, Applicant requests that the rejection of claims 63-65 under 35 U.S.C. § 103(a) be withdrawn.

### CONCLUSION

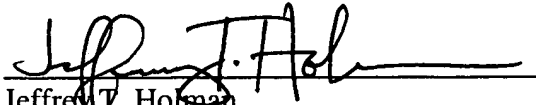
It is respectfully submitted that in view of the amendments and remarks set forth herein, the rejections have been overcome. If the Examiner believes a telephone interview would expedite the prosecution of this application, the Examiner is invited to contact Jeffrey Holman at (408) 720-8300.

If there are any additional charges, please charge them to Deposit Account No. 02-2666.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Date: 9/15/06

  
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